02-23-00

A

PATENT

Date February 22, 2000

Docket No. 16581-1864

CERTIFICATION UNDER 37 CFR 1.10

I hereby certify that this New Application Transmittal and the documents referred to as enclosed therein are being deposited with the United States Postal Service on February 22, 2000 in an envelope as "Express Mail Post Office to Addressee" Mail Label Number EL451117865US addressed to: Box Patent Application, Assistant Commissioner of Patents, Washington, D.C. 20231.

Amy Bresnahan
(Type name of person mailing paper)

(Signature of person mailing paper)

NOTE: Each paper or fee referred to as enclosed herein has the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 CFR 1.10(b).

Box Patent Application
Assistant Commissioner of Patents
Washington, D.C. 20231

NEW APPLICATION TRANSMITTAL

Transmitted herewith for filing is the patent application of

Inventor(s): Susan L. Bragg and Danny D. Meyer

For : METHOD OF PERFORMING SPECTRAL ANALYSIS IN A PHARMACEUTICAL DISSOLUTION PROCESS

Enclosed are:

1. Benefit of Prior U.S. Application (35 USC 120)

____ The new application being transmitted claims the benefit of a prior U.S. application and enclosed is added page for new application transmittal where benefit of a prior U.S. application claimed.

2. The Papers Required For Filing Under 37 CFR 1.53:

8 Pages of Specification
1 Pages of Abstract
4 Pages of Claims
2 Sheets of Drawing

___ formal X informal

In addition to the above papers there is also attached:
____ Pages of an Amendment
X Return Receipt Postcard
____ Information Disclosure Statement with ___ copies of references.

3. Declaration or oath

_X_ Enclosed _4_ pages
- _X_ Newly executed (original or copy)
- ____ Copy from a prior application (continuation/divisional with page 5 of 5 completed)
- ____ Deletion of Inventor(s) (signed statement attached deleting inventor(s) of prior application)

____ Not enclosed

4. Inventorship Statement

The inventorship for all the claims in this application are:

_X_ the same

OR

____ are not the same and an explanation, including the ownership of the various claims at the time the last claimed invention was made, is submitted.

5. Language

_X_ English ____ Non-English

A verified English translation of the

[check applicable item(s)]

____ specification and claims

____ declaration

is attached.

6. Assignment

_X_ An assignment of the invention to SpectraAlliance, Inc.

- _X_ is filed under separate cover sheet
- ____ was filed in the prior application
- ____ will follow

7. Certified Copy

_____
(Country) (Application No.) (Filed)

from which priority is claimed

____ is attached

____ will follow

8. Fee Calculation

CLAIMS AS FILED

	Number Filed	Provided with Basic Fee	Number Extra	Rate	Basic Fee $690
Total Claims	18	20	0	X $18.00	$ .00
Independent Claims	3	3	0	X $78.00	$ .00
Multiple Dependent Claim(s), if any	0	0	0	X $260.00	$ .00

____ Amendment canceling extra claims enclosed

____ Amendment deleting multiple dependencies enclosed

____ Fee for extra claims is not being paid at this time

Filing Fee Calculation $ 690.00

9. Small Entity Statement

__X__ verified statement that this is a filing by a small entity under 37 CFR 1.9 and 1.27 is attached.

Filing Fee Calculation (50% of above) $345.00

10. Fee Payment Being Made At This Time

__X__ Enclosed

__X__ basic filing fee $ 345.00

Total fees enclosed $ 345.00

11. Method of Payment of Fees

__X__ check in the amount of $ 345.00

12. Authorization to Charge Additional Fees

X The Commissioner is hereby authorized to charge the following additional fees which may be required to Account No. 18-1829;

X 37 CFR 1.16 (filing fees and presentation of extra claims)

X 37 CFR 1.17 (application processing fees)

___ 37 CFR 1.18 (issue fee at or before Mailing of Notice of Allowance, pursuant to 37 CFR 1.311(b).

13. Instructions As To Overpayment

X credit Account No. 18-1829

14. Correspondence Address

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Express Mail No. EL451117865US
PATENT

Applicants: Susan L. Bragg and Danny D. Meyer
Attorney's Docket No.: 16581-1864
Filed: Herewith
For: *METHOD OF PERFORMING SPECTRAL ANALYSIS IN A PHARMACEUTICAL DISSOLUTION PROCESS*

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS
[37 CFR 1.9(f) and 1.27(c)]
SMALL BUSINESS CONCERN

I hereby declare that I am:

____ the owner of the small business concern identified below:
__X__ an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF CONCERN: SpectraAlliance, Inc.
ADDRESS: 7534 Watson Road
St. Louis, Missouri 63119

I hereby declare that the above-identified small business concern qualifies as a small business concern as defined in 13 CFR 121.3-18, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees under section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention, entitled *METHOD OF PERFORMING SPECTRAL ANALYSIS IN A PHARMACEUTICAL DISSOLUTION PROCESS*,
by inventor(s): Susan L. Bragg and Danny D. Meyer

described in:

__X__ the specification filed herewith.
____ Application Serial No. __, filed _.
____ Patent No. __, issued __.

If the rights held by the above-identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed below and no rights to the invention are held by any person, other than the inventor, who could not qualify as a small business concern under 37 CFR 1.9(d) or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

NAME:
ADDRESS:

____ INDIVIDUAL ____ SMALL BUSINESS CONCERN ____ NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. [37 CFR 1.28(b)].

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING: Susan L. Bragg, Ph.D.
TITLE OF PERSON OTHER THAN OWNER: President
ADDRESS OF PERSON SIGNING: 7534 Watson Road
St. Louis, Missouri 63119

SIGNATURE: Susan L Bragg DATE: 21 Feb 00

Express Mail No. EL451117865US

METHOD OF PERFORMING SPECTRAL ANALYSIS IN A PHARMACEUTICAL DISSOLUTION PROCESS

Background Of The Invention

This invention relates generally to methods of performing spectral analysis in a pharmaceutical dissolution process, and more particularly to such methods using fiber optic probes.

Dissolution monitoring is used to determine the concentration of a pharmaceutical active ingredient as a function of time. Dissolution testing is an FDA requirement and an important step in the drug development process. A tablet, for example, is dropped into a temperature-controlled reservoir containing an aqueous solution. The concentration of the active ingredient in solution is measured as the tablet dissolves. The concentration can be determined through an optical spectroscopic measurement, primarily in the ultraviolet to visible portion of the spectrum. The sample is either removed from the reservoir for measurement or an in situ measurement probe is inserted into the reservoir.

In situ measurements offer increased measurement efficiency, while potentially reducing measurement errors due to extraction. In situ probes use fiber optic coupling to connect the measurement probe to both the light source and the detecting spectrometer.

Dissolution testing is usually performed automatically using apparatus designed to sample continuously or discretely from dissolution vessels. In a continuous sampling procedure, a single fiber optic probe per dissolution vessel is employed. In a discrete sampling procedure, a fiber optic probe is

used for sampling in a plurality of dissolution vessels. A robot arm dips the probe in a first dissolution vessel where optic measurements are made to measure certain properties of a dissolution solution in the dissolution vessel. The robot arm then moves the probe from the first dissolution solution to a bath where the probe is cleaned, and then dips the probe into a second dissolution vessel for measuring certain properties of a second dissolution solution.

A disadvantage of prior art probes used in dissolution testing is that air occasionally becomes trapped in a sampling region of the probe (e.g., adjacent a lens or window). The trapped air impedes accurate spectral analysis of the dissolution solution.

Summary Of The Invention

Among the objects and advantages of the present invention may be noted the provision of an improved method for performing spectral analysis in a pharmaceutical dissolution process; and the provision of such a method employing a fiber optic probe which minimizes entrapment of air within the probe sample region.

Generally, a method of the present invention is for performing spectral analysis in a pharmaceutical dissolution process. The method comprises inserting a fiber optic probe of a spectral analyzer into a dissolution vessel. The dissolution vessel contains a dissolution medium. The probe has a launch cable, a return cable, a launch lens portion, a return lens portion and a reflector. The cables, lens portions and reflector are arranged and adapted to form a light pathway whereby light transmitted through the launch cable passes through the launch lens portion, through a volume of the dissolution media in the spacing between the launch lens portions and the reflector, then through the return cable. The spacing between the reflector and the lens portions comprise a sample region. The fiber optic probe is sized and adapted to prevent bubbles in the dissolution media from being trapped in the sample region. The method further comprises transmitting light along the optic pathway, and analyzing the transmitted light for determining certain optical properties of the dissolution media in the sample region.

Another aspect of the present invention is a method of making a fiber optic probe. The method comprises placing into a sheath a launch cable, a return cable, a launch lens portion, a return lens portion, and a reflector. The launch lens portion is forward of and aligned with the launch cable. The return lens portion is forward of and aligned with the return cable. The launch lens portion has a focal length substantially equal to the focal length of the return lens portion. The sheath has an end margin extending forward from the lens portions and terminating in a sheath end. The end margin of the sheath has at least one slot therein. The method further comprises: positioning a reflector element adjacent the sheath end and spaced from the lens portions by the desired sample region length; placing the return cable into optical communication with an optical detector; transmitting light along the launch cable through the launch lens portion and to the reflector element; adjusting the position of the reflector element relative to the sheath to substantially maximize detection by the detector of the transmitted light reflected from the reflector through the return lens portion and through the return cable and to the detector; and securing the reflector element to the sheath to maintain the reflector element in its adjusted position.

Other objects and features will be in part apparent and in part pointed out herinafter.

Brief Description Of The Drawings

Fig. 1 is a schematic of a dissolution system of the present invention, the dissolution system comprising a dissolution vessel containing a dissolution media, and a spectral analyzer;

Fig. 2 is an enlarged, longitudinal, cross-sectional view of a fiber optic probe of the spectral analyzer of Fig. 1; and

Fig. 3 is a cross-sectional view taken along the plane of line 3-3 of Fig. 2.

Corresponding reference characters indicate corresponding parts throughout the several views of the drawings.

Description Of The Preferred Embodiment

Referring to Fig. 1, a dissolution process of the present invention employs a dissolution vessel 20, a dissolution medium 22 contained within the dissolution vessel, a paddle 28 extending into the vessel for mixing the dissolution medium 22, and a spectral analyzer, generally indicated at 26. The dissolution medium 22 is preferably simulated biological fluids with pharmaceutical formulations being dissolved therein. A paddle 28 extends into the dissolution medium 22 for mixing the dissolution medium. The spectral analyzer 26 includes a fiber optic probe, generally indicated at 30, and an analyzer 32. The probe 30 is adapted to extend downward into the dissolution media and is in optic communication with the analyzer 32. Light energy from the analyzer 32 is transmitted along an optical pathway via the probe 30 through a sample of the dissolution medium 22 and returned to the analyzer where it is analyzed for determining certain optical properties of the dissolution medium. The optical properties may enable a user to determine release rates and/or other properties of the pharmaceutical formulations.

Referring now to Fig. 2, the probe 30 comprises a launch (or lamp) cable 34, a return (or detector) cable 36, a launch lens portion 38 aligned with the launch cable, a return lens portion 40 aligned with the return cable, a reflector element 42, and a sheath 44. The cables 34, 36, the lens portions 38, 40 and the reflector 42 are arranged and adapted to form a light pathway whereby light transmitted through the launch cable passes through the launch lens portion, through a volume of the dissolution media in the spacing between the launch lens portions and the reflector, through the return lens portion, through the return cable and to a detector (not shown) of the analyzer 32.

Each of the launch and return cables 34, 36 are preferably conventional fiber optic cables having one or more fibers. The fiber optic cables may also be specialized cables, such as those that minimize solarization. The cables 34, 36 extend into the sheath 44 generally along a probe axis X. The cables 34, 36 are of sufficient length to allow easy attachment to the spectral analyzer and are terminated with a conventional

fiber optic connector, such as an SMA 905. The cables 34, 36 are supported and strain relieved at the rearward end of the probe by a handle assembly 56. The launch and return lens portions 38, 40 are preferably portions of a single monolithic lens 46. Alternatively, the launch and return lens portions 38, 40 may be separate lenses. Preferably, the lens 46 is of a synthetic fused silica. Alternatively, the lens 46 could be of sapphire, quartz or any other suitable lens material. The lens 46 is preferably secured to a forward end of a lens/fiber holder assembly 48, and forward ends of the cables 34, 36 are preferably secured to a rearward end of the holder assembly. Cables 34, 36 are preferably spaced from the lends 46 by a distance equal to the focal length of the lens 46. The reflector element 42 preferably includes a mirror 50 secured to a mirror holder 52. The mirror 50 preferably includes a highly reflective surface. The reflector element 42 is secured to a forward end of the sheath 44 and is preferably spaced from the lens by the desired sample region path length. Although the reflector element 42 preferably includes a mirror, it is to be understood that other components could be used instead of the mirror without departing from the scope of this invention. For example, the reflector element could instead comprise a prism (not shown) configured to reflect light from the launch lens portion to the return lens portion. The sheath 44 includes at least one and preferably two slots (or openings) 54 (only one of which is shown in Fig. 2) for permitting fluid (e.g., the dissolution medium) to flow between the lens 46 and mirror 50. The slots 54 are preferably on opposite sides of a forward end margin of the sheath 44 to allow fluid to flow through the end margin of the sheath. Also preferably, the slots 54 extend from the lens 46 forward to the mirror 50.

The fiber optic probe 30 is sized and adapted to prevent bubbles in the dissolution medium from being trapped in the sample region (e.g., from being trapped against the surface of the lens 46). Preferably, each cross-sectional dimension of the probe 30 lying in a plane perpendicular to the probe axis X and between the reflector element 42 and the lens 46 are equal to or less than approximately 5 millimeters (mm), and more preferably equal to or less than approximately 4 mm. In the preferred embodiment, such a cross-

sectional view is shown in Fig. 3. In this embodiment, the largest such cross-sectional dimension is the outer diameter of the sheath 44. Thus, the outer diameter of the shroud is preferably equal to or less than approximately 5 mm, and more preferably equal to or less than approximately 4 mm. The small diameter of the probe 30 confers many features. The probe 30 is minimally invasive; its small diameter makes accurate measurements possible without perturbing the system to be measured. In addition, the small diameter of the probe means that the sample volume (i.e., the volume between the lens 46 and mirror 50 and bounded by the sheath 44) is much smaller than conventional probes used in dissolution testing. The sample volume is only 40% as large as that of a probe having a ¼" (6.3 mm) diameter, and only 10% as large as that of a probe having a ½" (12.7 mm) diameter. This small volume (about 12 mm^3 for a 10 mm optical path-length probe means that a concomitantly smaller volume of air has the opportunity to be trapped within the sample volume when the probe is inserted. A smaller volume of trapped air reduces the likelihood of producing bubbles on the probe optics.

Air bubbles formed in liquids also tend to have characteristic dimensions that depend on the properties of the liquid. Bubbles tend to form in the lowest energy configuration possible, with a larger bubble having a lower energy. Small bubbles may coalesce to form larger bubbles. The small diameter of the probe 30 does not physically support large bubbles, if they should form during probe insertion. Large bubbles will tend to float off, or break, rather than be trapped by the probe optics. Larger diameter probes better support and retain large diameter bubbles which have been formed during insertion.

In making the fiber optic probe 30, the launch cable 34, return cable 36, lens 46, and the reflector element 42 are placed into the sheath 44. The launch lens portion 38 of the lens 46 is forward of and spaced from the launch cable 34. The return lens portion 40 of the lens 46 is forward of and spaced from the return cable 36. The launch lens portion 38 preferably has a focal length substantially equal to the focal length of the return lens portion 40. The lens 46 is preferably secured via the lens holder 48 to the sheath and in

registration with the slots 54. Cables 34, 36 are preferably secured in lens holder 48 rearward of the lens portions at a distance approximately equal to the focal length of the lends 46. The reflector element 42 is positioned adjacent the sheath end (i.e., the forward-most end, or the left-most end as viewed in Fig. 2) of the sheath and spaced from the lens 46 a distance corresponding the desired sample path length, for example 5mm. The return cable 36 is placed into optical communication with the optical detector of the analyzer 32. Light energy is then preferably transmitted along the launch cable 34 through the lens 46 and to the reflector element 42. The position of the reflector element 42 relative to the sheath 44 is then adjusted to substantially maximize detection by the detector of the transmitted light reflected from the reflector through the return lens portion and through the return cable and to the detector. In other words, the reflector element 42 is tilted and/or moved axially along the probe axis X until the maximum amount of reflected light energy is transmitted through the return cable 36 to the detector. The reflector element 42 is then permanently secured in such position to the sheath to maintain the reflector element in such position. Preferably, the reflector element 42 is secured to the sheath via a suitable, chemical-resistant epoxy such as that sold by product number EP21ARSP-1, commercially available from Masterbond, of Hackensack, New Jersey.

In operation, the launch cable 34 of the probe 30 is in optical communication with a light source (not shown) in the analyzer 32, and the return cable 36 is in optical communication with a detector (not shown) of the analyzer. The forward-most portion of the probe 30 is inserted into the dissolution medium 22 in the dissolution vessel 20. Light energy is transmitted from the light source, through the launch cable 34, through the lens 46, through the dissolution media between the lens and reflector element 42 and to the reflector element where it is reflected through the dissolution medium again, then to the lens and transmitted to the detector via the return cable 36. The transmitted light received by the detector is then analyzed for determining the optical properties of the dissolution media.

In view of the above, it will be seen that the several objects of the invention are achieved and other advantageous results attained.

As various changes could be made in the above constructions and methods without departing from the scope of the invention, it is intended that all matter contained in the above description or shown in the accompanying drawings shall be interpreted as illustrative and not in a limiting sense.

What is claimed is:

1. A method of performing spectral analysis in a pharmaceutical dissolution process, the method comprising:

inserting a fiber optic probe of a spectral analyzer into a dissolution vessel, the dissolution vessel containing a dissolution medium, the probe having a launch cable, a return cable, a launch lens portion, a return lens portion and a reflector, the reflector being spaced from both the lens portions, the cables, lens portions and reflector being arranged and adapted to form a light pathway whereby light transmitted through the launch cable passes through the launch lens portion, through a volume of the dissolution media in the spacing between the launch lens portions and the reflector, through the return lens portion, and then through the return cable, the spacing between the reflector and the lens portions comprising a sample region, the fiber optic probe being sized and adapted to prevent bubbles in the dissolution media from being trapped in the sample region;

transmitting light along the optic pathway;

analyzing the transmitted light for determining certain optical properties of the dissolution media in the sample region.

2. A method as set forth in claim 1 wherein the probe further comprises a sheath portion, the sheath portion containing the lens portions and reflector, the sheath portion having a diameter equal to or less than approximately 5 mm.

3. A method as set forth in claim 2 wherein the sheath portion has a diameter equal to or less than approximately 4 mm.

4. A method as set forth in claim 1 wherein the launch lens portion and the return lens portion are portions of a single monolithic lens.

5. A method as set forth in claim 1 wherein the launch and return cables extend generally along a probe axis, each cross-sectional dimension of the probe lying in a plane perpendicular to the probe axis and between the reflector and the lens portions is equal to or less than approximately 5 mm.

6. A method as set forth in claim 1 wherein the launch and return cables extend generally along a probe axis, each cross-sectional dimension of the probe lying in a plane perpendicular to the probe axis and between the reflector and the lens portions is equal to or less than approximately 4 mm.

7. A method as set forth in claim 1 wherein the reflector is a mirror.

8. A method as set forth in claim 1 wherein the launch lens portion is generally aligned with an end of the launch cable, and wherein the return lens portion is generally aligned with an end of the return cable.

9. A method of performing spectral analysis in a pharmaceutical dissolution process, the method comprising:

inserting a fiber optic probe of a spectral analyzer into a dissolution vessel, the dissolution vessel containing a dissolution medium, the probe having a launch cable, a return cable, a launch lens portion, a return lens portion and a reflector, the launch and return cables extending generally along a probe axis, the reflector being spaced from both the launch lens portion and the return lens, the cables, lens portions and reflector being arranged and adapted to form a light pathway whereby light transmitted through the launch cable passes through the launch lens, through a volume of the dissolution medium in the spacing between the lens portions and the reflector, through the return lens, and then through the return cable, the spacing between the reflector and the lens portions comprising a sample region, each cross-sectional dimension of the probe lying in a plane perpendicular to the probe axis and between the reflector and the lens portions being equal to or less than approximately 5 mm;

transmitting light along the optic pathway;

analyzing the transmitted light for determining certain optical properties of the dissolution media in the sample region.

10. A method as set forth in claim 9 wherein the launch lens portion is generally aligned with a forward end of the launch cable, and wherein the return lens portion is generally aligned with a forward end of the return cable.

11. A method as set forth in claim 10 wherein each cross-sectional dimension of the probe lying in a plane perpendicular to the probe axis and between the reflector and the lens portions is equal to or less than approximately 4 mm.

12. A method as set forth in claim 10 wherein the probe further comprises a sheath portion, the sheath portion containing the lens portions and reflector, the sheath portion having a diameter equal to or less than approximately 5 mm.

13. A method as set forth in claim 12 wherein the sheath portion has a diameter equal to or less than approximately 4 mm.

14. A method of making a fiber optic probe comprising:

placing into a sheath a launch cable, a return cable, a launch lens portion, a return lens portion, and a reflector, the launch lens portion being forward of and aligned with the launch cable, the return lens portion being forward of and aligned with the return cable, the launch lens portion having a focal length substantially equal to the focal length of the return lens portion, the sheath having an end margin extending forward from the lens portions and terminating in a sheath end, the end margin of the sheath having at least one slot therein;

positioning a reflector element adjacent the sheath end;

placing the return cable into optical communication with an optical detector;

transmitting light along the launch cable through the launch lens portion and to the reflector element;

adjusting the position of the reflector element relative to the sheath to substantially maximize detection by the detector of the transmitted light reflected from the reflector through the return lens portion and through the return cable and to the detector;

securing the reflector element to the sheath to maintain the reflector element in its adjusted position.

15. A method as set forth in claim 14 wherein the slot extends forward to the reflector element.

16. A method as set forth in claim 14 wherein the sheath has a diameter equal to or less than approximately 5 mm.

17. A method as set forth in claim 14 wherein the sheath has a diameter equal to or less than approximately 4 mm.

18. A method as set forth in claim 14 wherein the launch lens portion and the return lens portion are portions of a single monolithic lens.

METHOD OF PERFORMING SPECTRAL ANALYSIS IN A PHARMACEUTICAL DISSOLUTION PROCESS

Abstract Of The Disclosure

A method for performing spectral analysis in a pharmaceutical dissolution process. The method comprises inserting a fiber optic probe of a spectral analyzer into a dissolution vessel. The dissolution vessel contains a dissolution medium. The probe has a launch cable, a return cable, a launch lens portion, a return lens portion and a reflector. The reflector is spaced from both the lens portions. The cables, lens portions and reflector are arranged and adapted to form a light pathway whereby light transmitted through the launch cable passes through the launch lens portion, through a volume of the dissolution medium in the spacing between the launch lens portions and the reflector, and then through the return cable. The spacing between the reflector and the lens portions comprise a sample region. The fiber optic probe is sized and adapted to prevent bubbles in the dissolution medium from being trapped in the sample region. The method further comprises transmitting light along the optic pathway, and analyzing the transmitted light for determining certain optical properties of the dissolution medium in the optic pathway.

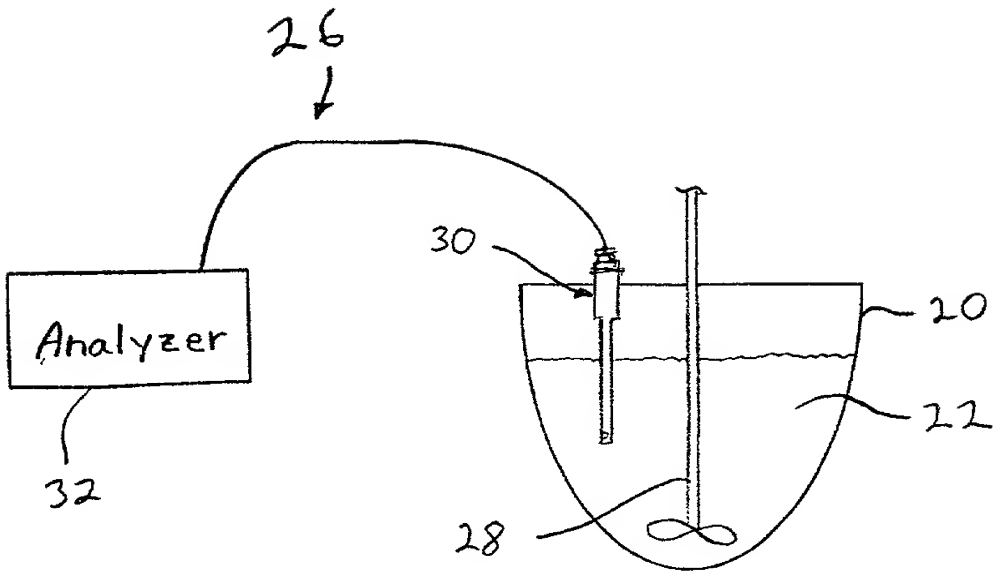

Fig. 1

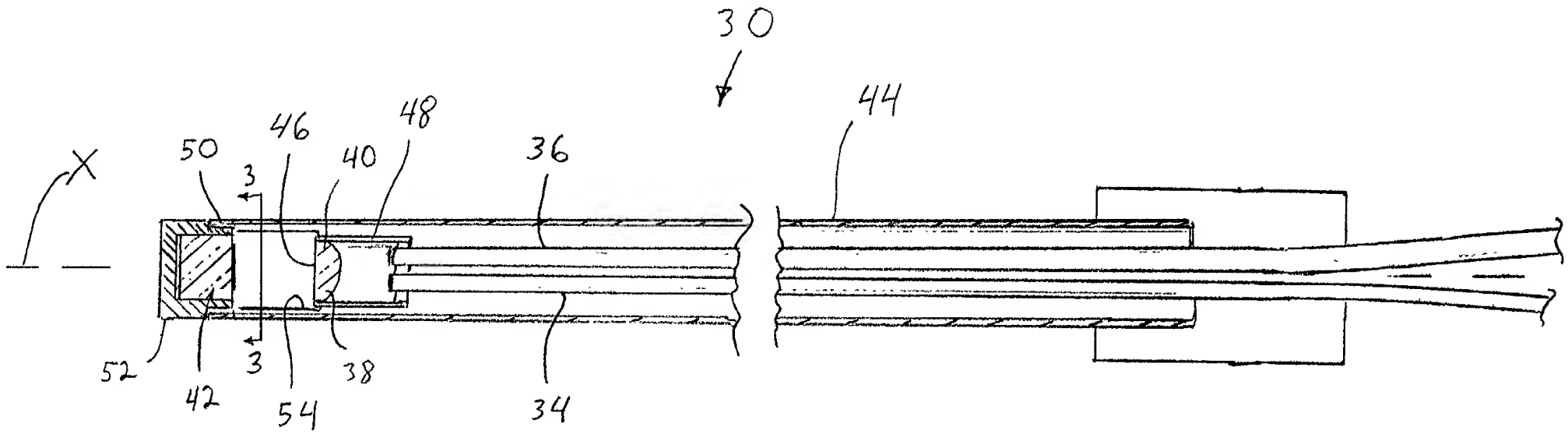

Fig. 2

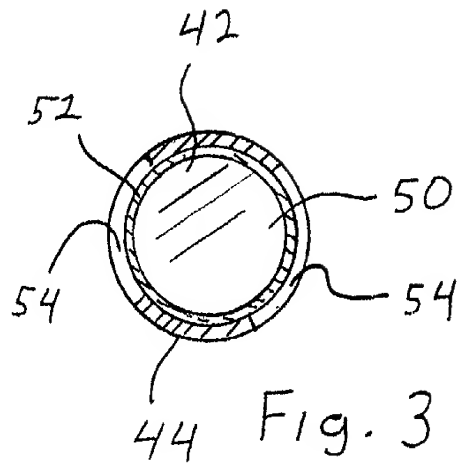

Fig. 3

PATENT
Express Mail No. EL451117865US
Attorney's Docket No. 16581-1864

COMBINED DECLARATION AND POWER OF ATTORNEY

(Original, Design, National Stage of PCT or CIP Application)

Inventors: Susan L. Bragg and Danny D. Meyer

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are stated below next to my name, I believe I am the original, first and sole inventor (if only one name is listed above) or an original, first and joint inventor along with those listed above (if plural names are listed above) of the subject matter which is claimed and for which a patent is sought on the invention entitled: *METHOD OF PERFORMING SPECTRAL ANALYSIS IN A PHARMACEUTICAL DISSOLUTION PROCESS*

the specification of which: (Complete (a), (b) or (c) for type of application)

REGULAR OR DESIGN APPLICATION

(a) X is attached hereto.

(b) ____ was filed on _ as Application Serial No. _ and was amended on _ (if applicable).

PCT FILED APPLICATION ENTERING NATIONAL STAGE

(c) ____ was described and claimed in International Application No. _ filed on _ and as amended on _ (if any).

ACKNOWLEDGEMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations §1.56.

____ In compliance with this duty there is attached an information disclosure statement. 37 CFR 1.97.

PRIORITY CLAIM

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed.

[Complete (d) or (e)]

(d) __X__ no such applications have been filed.

(e) ____ such applications have been filed as follows.

EARLIEST FOREIGN APPLICATION(S), IF ANY FILED WITHIN 12 MONTHS
(6 MONTHS FOR DESIGN) PRIOR TO SAID APPLICATION

Country	Application No.	Date of filing (day, month, year)	Date of issue (day, month, year)	Priority Claimed
				___YES NO ___
				___ YES NO ___

ALL FOREIGN APPLICATION(S), IF ANY FILED MORE THAN 12 MONTHS
(6 MONTHS FOR DESIGN) PRIOR TO SAID APPLICATION

CLAIM FOR BENEFIT OF PRIOR U.S. PROVISIONAL APPLICATION(S)

I hereby claim the benefit under Title 35, United States code, § 119(e) of any United States provisional application(s) listed below:

(Provisional Application Number)	(Filing Date)
(Provisional Application Number)	(Filing Date)
(Provisional Application Number)	(Filing Date)

CONTINUATION-IN-PART

(Complete this part only if this is a continuation-in-part application)

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application.

(Application Serial No.) (Filing Date) (Status) (Patent, pending, abandoned)

(Application Serial No.) (Filing Date) (Status) (Patent, pending, abandoned)

POWER OF ATTORNEY

As a named inventor, I hereby appoint the following attorney and/or agent to prosecute this application and transact all business in the U.S. Patent and Trademark Office connected therewith, before all competent international authorities in connection with any international application, and before all foreign patent offices in connection with the national phase of any international application or any foreign application, and to appoint any associate attorneys in connection with any application, either domestic, international or foreign national.

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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